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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,178	09/25/2001	Robert Raffa	TUN-566US	9598

7590 12/29/2003
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EXAMINER

MAIER, LEIGH C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/964,178

Applicant(s)

RAFFA ET AL.

Examiner

Leigh C. Maier

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 11, 12 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11, 12 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

Claims 8-10 have been canceled. Claims 1, 11, and 16 have been amended. Claims 1-6, 11, 12, and 14-16 are pending. Any objection or rejection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1, 11, 12, and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 16 recite weight ratios "based on glucosamine sulfate as the glucosamine as the glucosamine material." It is unclear if this is the recited weight ratio (claim 1) or range of weight ratios (claim 16) is required for the full scope of glucosamine materials or only when glucosamine sulfate is the glucosamine material. The claims are thus rendered vague and indefinite. From a reading of the paragraph bridging pages 4 and 5 of the remarks, it appears that Applicant intends it to mean the full scope of glucosamine material, but the claim, as written remains unclear.

Claim Rejections - 35 USC § 102

Claim 1 is again rejected under 35 U.S.C. 102(e) as being anticipated by GIORGETTI (US 6,291,527), as set forth previously.

The invention is as set forth in the previous Office action. The claim has been amended to add a limitation to the composition: "the weight ratio of glucosamine material to said analgesic is about 2:1 or more based on glucosamine sulfate as the glucosamine as the glucosamine material." The limitation excluding specific counterions has been deleted.

Applicant's arguments filed October 6, 2003 have been fully considered but they are not persuasive. Applicant argues that the amended claims require a glucosamine:analgesic ratio well above that disclosed by the reference. As discussed above, the claims have been amended in such a way rendering them indefinite. As amended, a fair reading of the claim would allow for the recited ratio to apply only when glucosamine sulfate is the glucosamine material.

Claim Rejections - 35 USC § 103

Claims 1, 14, and 15 are again rejected under 35 U.S.C. 103(a) as being unpatentable over PARADIES (US 5,604,206) as set forth in the previous Office action.

The invention is as set forth above.

Applicant's arguments filed October 6, 2003 have been fully considered but they are not persuasive.

Applicant first contends that the disclosed substances do not involve salt formation. This is immaterial as no salt formation is required. Applicant also argues that the amended claims

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require a glucosamine:analgesic ratio well above that disclosed by the reference. This argument was addressed above.

Claims 1-6, 11, 12, and 14-16 are again rejected under 35 U.S.C. 103(a) as being unpatentable over PETRUS (US 6,399,093) in view of either GIORGETTI (US 6,291,527) or PARADIES (US 5,604,206) as set forth in the previous Office action.

The invention is as set forth above.

Applicant's arguments filed October 6, 2003 have been fully considered but they are not persuasive.

Applicant argues that PETRUS specifically teaches away from an oral dosage form. To support this contention, Applicant cites two passages from the reference, set forth at page 6 or the remarks. The examiner agrees that the reference teaches that in some cases, topical application has advantages for localized pain and inflammation. However, systemic (oral) administration of this combination of agents is known in the art, as taught by either GIORGETTI or PARADIES. The examiner maintains that one of ordinary skill would reasonably expect success in reformulating the weight ratios taught by PETRUS into oral dosage forms with a reasonable expectation of success.

Applicant further contends that motivation to combine is not found in either GIORGETTI or PARADIES. It appears that the argument is that the references cannot be combined because PETRUS is limited to topical administration and both GIORGETTI and PARADIES are limited to oral administration. The examiner disagrees with this characterization of the latter two

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references. Both GIORGETTI (see examples 4-15 and 27-30) and PARADIES (see col 3, beginning line 55, continuing through col 4, line 32).

In response to Applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claims 1, 12, 14, and 15 are again rejected under 35 U.S.C. 103(a) as being unpatentable over GIORGETTI (US 6,291,527) as set forth in the previous Office action.

The invention is as set forth above.

Applicant's arguments filed October 6, 2003 have been fully considered but they are not persuasive. The arguments are the same as those regarding the anticipation rejection over GIORGETTI and have been discussed above.

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's hours, phone & fax numbers

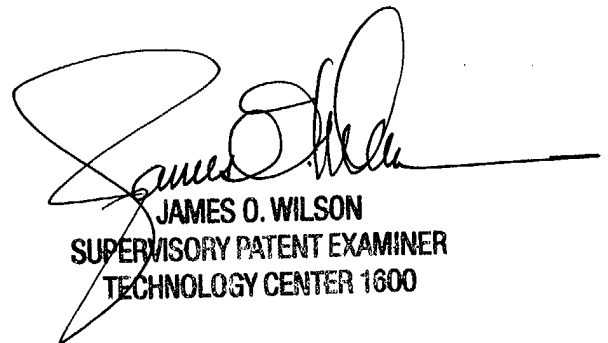
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (703) 308-4624, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
December 19, 2003



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600